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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,093	03/16/2001	Stephanie K. Clendennen	4257-0025.30	8290
23500	7590	01/30/2004	EXAMINER	
JAN P. BRUNELLE EXELIXIS, INC. 170 HARBOR WAY P.O. BOX 511 SOUTH SAN FRANCISCO, CA 94083-0511			MEHTA, ASHWIN D	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 01/30/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/811,093

Applicant(s)

CLENDENNEN ET AL.

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,9-12,15 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7,9-12,15 and 19-23 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10282002
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1638

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The objection to the specification is withdrawn, in light of Applicant's argument demonstrating that the sequence of SEQ ID NO: 46 is the same sequence that appeared in GenBank Accession No. Z70522 at the time the application was filed.

### ***Claim Objections***

3. Claim 5 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 112***

4. Claims 1, 7, 9-12, 15, and 19-23 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed October 1, 2003. Applicants traverse the rejection in the paper submitted November 3, 2003. Applicants' arguments have been fully considered but were not found persuasive.

Art Unit: 1638

Applicants argue that the Examiner again failed to provide an explanation as to why a person skilled in the art would not recognize that the written description of the invention provides support for the claims, and assert that the initial burden of providing a proper rejection under the written description requirement under 35 U.S.C. 112 was not met (response, page 2, 1<sup>st</sup> full paragraph). The Examiner maintains that the previous Office actions provided a proper rejection following the written description guidelines.

Applicant address a comment made by the Examiner in the previous Office action, concerning Exhibits B-D, which were submitted with the previous response on July 22, 2003. Exhibits B-D present abstracts of journal articles. Applicants comment that the purpose of submitting the abstracts was to demonstrate that given a promoter-containing nucleotide sequence, one skilled in the art knows that sub-fragments of the sequence that retain promoter activity can be readily identified (response, page 2, 2<sup>nd</sup> full paragraph). However, unlike the articles belonging to the abstracts of Exhibits B-D, the instant specification does not describe the nucleotide sequences of any portions SEQ ID NO: 42, other than nucleotides 156-1708, that retain its fruit-associated transcriptional activity.

5. Claims 1, 7, 9-12, 15, and 19-23 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a portion of SEQ ID NO: 42 consisting of nucleotides 156-1708 that directs fruit-associated transcription, does not reasonably provide enablement for any other portion of SEQ ID NO: 42 as having the functional activity of directing fruit-associated transcription. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, make and/or use the invention

Art Unit: 1638

commensurate in scope with these claims, for the reasons of record stated in the Office action mailed October 1, 2003. Applicants traverse the rejection in the paper submitted November 3, 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that they are not claiming the minimal promoter fragment of SEQ ID NO: 42 essential for fruit-associated expression, and that a showing of "essential" regions responsible for the claimed promoter activity is not necessary (response, page 3, 1<sup>st</sup> full paragraph). However, claim 1 encompasses any portion of SEQ ID NO: 42 that directs fruit-associated expression. This encompasses the minimal promoter fragment that retains this activity. Further, knowledge of the essential regions is necessary, since every fragment of SEQ ID NO: 42 that retains the fruit-associated transcriptional activity must have them.

Applicants argue that given the size of the sequence and the location of the TATA box, one would just have to make just a few 5' deletions to approximate the length of the necessary sequence. Applicants cite Adams et al. (provided in Exhibit B) for the teaching that six deletion derivatives of a tissue-specific promoter were produced, to ascertain the region responsible for the tissue-specific activity. Applicants also cite Golden et al. (provided in Exhibit C) for teaching that nine deletion constructs of the 5' UTR of the human endothelin-1 gene were made to determine regions necessary for basal regulation, thrombin-stimulated induction, and full expression of a reporter gene. Applicants argue that since the starting sequences used in Adams et al. and Golden et al. were significantly larger than the instant 1735 bp sequence, that it is reasonable to assume that one skilled in the art would not have to make very many fragments in order to further characterize the region of the promoter responsible for fruit-associated expression (response, page 3, 2<sup>nd</sup> full paragraph). However, the claims are not limited to only 6

Art Unit: 1638

or 9 subfragments. Further, claim 1 encompasses any portion of SEQ ID NO: 42 that retains fruit-associated expression, not just 5' deletions.

### *Summary*

6. Claim 5 remains objected to, and claims 1, 7, 9-12, 15, and 19-23 remain rejected.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Contact Information*

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy

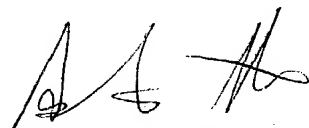
Application/Control Number: 09/811,093

Page 6

Art Unit: 1638

Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 12, 2004

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta', is positioned above the printed name.

Ashwin D. Mehta, Ph.D.  
Primary Examiner  
Art Unit 1638